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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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AVON PLACE			WANG, SHENGJUN	
SUFFERN, NY 10901			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)		
	10/738,411	MCKIE ET AL.		
Office Action Summary	Examiner	Art Unit		
	Shengjun Wang	1617		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
 1) ☐ Responsive to communication(s) filed on <u>03 Fe</u> 2a) ☐ This action is FINAL. 2b) ☐ This 3) ☐ Since this application is in condition for allowar closed in accordance with the practice under E 	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) Claim(s) 1-43 is/are pending in the application. 4a) Of the above claim(s) 22,26,42 and 43 is/ar 5) Claim(s) is/are allowed. 6) Claim(s) 1-21,23-25 and 27-41 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or Application Papers 9) The specification is objected to by the Examinet 10) The drawing(s) filed on is/are: a) access	re withdrawn from consideration.	Examiner.		
Applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction 11). The oath or declaration is objected to by the Ex.	ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).		
<i>,</i> — • •	anniner. Note the attached Office	Action of Iomi F 10-132.		
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	nte		

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 3, 2009 has been entered.

Claim Rejections 35 U.S.C. 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-7, 23-25, 27-34, are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), Duffy et al. (US 5,472,699) and Wiegand et al. (US 2002/0151527, IDS).
- 4. Beerse et al. teaches a method of treating or preventing dandruff and acne comprising applying a topical composition comprising a benzoic acid derivatives, wherein the benzoic acid have hydroxyl, or halogen substituents at 2-6 positions, halogenated salicylic acids, such as 5-chlorosalicylic acid, 5-bromosalicylic acid, 5-fluorosalicylic acid, etc, are listed as preferred compounds. The amount of the benzoic acid derivative in the composition is in the range of 0.01-20%. See, particularly, the abstract; col. 3, lines 54-62; col. 6, lines 5-19; and the claims. Beerse

et al. further teaches that dimethicone may be incorporated into the topical composition. See, particularly, col. 10, lines 39-48. Other active and well known cosmetics agents may also incorporated into the topical compositions includes antioxidants, such as ascorbic acid (vitamin C) or its derivatives, thiols, such as ethane thiol, and lipoic acid. See, cols. 19-30, particularly, col. 28, lines 50-60; col. 30, lines 25-40.

- 5. Beerse et al. do not teach expressly the employment of the halogenated salicylic acids for treating the skin conditions associated with the acne.
- 6. However, Duennenberger et al. teaches that the salt of 5-chlorosalicylic acid is known to be an antimicrobial agents and useful in cosmetic composition. Wiegand et al. disclosed that sebum output, and bacterial infection is closely related to acne. Further, acne vulgaris would greatly affect skin appearance. See, particularly paragraphs 0007-0010. Perricone reveals that acne is associated with skin pore size and treatment of acne is also beneficial in reducing pore size. See, col. 3, lines 15-25. Duffy et al. discloses that skin pores are large and numerous on the face and scalp, with density of 400 to 800 pores/cm², compared with 50 pores/cm² on the arms and legs. See, col. 1, lines 20-62.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made, to employ the particular halogenated salicylic acids disclosed by Beerse et al. for treating subject with acne and/or dandruff.

A person of ordinary skill in the art would have been motivated to employ the particular halogenated salicylic acids disclosed by Beerse et al. for treating subject with acne and/or dandruff because the halogenated salicylic acid is known to be useful for treatment of acne.

Furthermore, one of ordinary skill in the art would have expected the halogenated salicylic acid

be useful against acne as an antimicrobial agent. It is further contended that it would have been obvious to apply the composition to skin area with acne and area without acne because the compound is known to prevent (or suppress) the development of acne. One of ordinary skill in the art would have been motivated to apply the compound to skin area with enlarged pore size (previously infected with acne) for preventing a relapse. Furthermore, since skin pores are numerous on skin, application of a topical composition on the skin of acne patients would have been reasonably expected to cover those enlarged pores associated with acne.

Furthermore, the optimization of a result effective parameter, e.g. the effective amounts of the active ingredients in a therapeutical method, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Finally, incorporation of other ingredients known to be useful in the composition, such as vitamin C, lipoic acid, dimethicone, would have been within the purview of ordinary skill in the art.

7. Claims 8, 9, 32 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), Duffy et al. (US 5,472,699) and Wiegand et al. (US 2002/0151527, IDS), for reasons discussed above, and in further view of O'Halloran et al. (US 6,168,798).

The prima references as a whole, do not teach expressly the employment of salicylic acid, and/or lactic acid for the treatment of acne and associated conditions.

However, O'Halloran et al. teach that β -hydroxyl-carboxylic acids, particularly, salicylic acid, and α -hydroxyl-carboxylic acid, such as lactic acid and glycolic acid, are useful for treating acne and skin conditions associated with acne. The effective amount of salicylic acid is about

0.1% to about 15% by weight of the total composition. See, particularly, the abstract, col. 2, lines 22-30, col. 4, line 56 to col. 5, lines 27, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ salicylic acid and/or lactic acid. with the halogenated salicylic acid for treatment of acne and associated skin conditions.

A person of ordinary skill in the art would have been motivated to further employ salicylic acid with the halogenated salicylic acid for treatment of acne and associated skin conditions because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See <u>In re Kerkhoven</u>, 205 USPQ 1069.

8. Claims 10-21 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), Duffy et al. (US 5,472,699) and Wiegand et al. (US 2002/0151527, IDS), for reasons discussed above, and in further view of Gormley et al. (US 6,174,892), Menon et al. (WO 01/66080).

The prima references as a whole, do no teach expressly teach the employment of phytol, finasteride, and/or retinol for the treatment of acne and associated conditions.

However, Gormley et al. teach that 5α -reductase inhibitors, such as finasteride, are useful for treatment of acne. See, particularly, the abstract, and the claims. Monen et al. teaches that phytol is useful for treatment of a variety of skin conditions, including acne and associated condition. See, particularly, page 2, line 20 to page 3, line 15. Phytol is particularly useful with

other well-known skin caring agents, such as retinoid, salicylic acid, 5-alpha-reductase inhibitor, such as saw palmetto and finasteride. See, particularly, pages 7-9.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ 5α -reductase inhibitors, such as finasteride, phytol, and/or retinol, with the halogenated salicylic acid for treatment of acne and associated skin conditions.

A person of ordinary skill in the art would have been motivated, to further employ 5α-reductase inhibitors, such as finasteride, phytol, and/or retinol, with the halogenated salicylic acid for treatment of acne and associated skin conditions because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See In re Kerkhoven, 205 USPQ 1069. Note the Anti-ageing active ingredients recited in claim 20 are defined to include anti-wrinkle agent, such as retinoid. See, page 1, lines 22-23, page 13, lines 10-20 of the specification.

9. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), Duffy et al. (US 5,472,699) and Wiegand et al. (US 2002/0151527, IDS), for reasons discussed above, and in further view of Ptchelintsev et al. (US 5,834,513).

The prima references as a whole, do no teach expressly teach the employment of ptrioxaundecanedioic acid for the treatment of acne and associated conditions.

However, Ptchelintsev et al. teaches that oxa diacids, trioxaundecanedioic acid in particular, are known to be useful for treatment of a variety of skin conditions, including acne, blemeshed skin, hyperkeratosis. See, particularly, col. 2, line 54 to col. 3, line 3, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ oxa diacids, such as trioxaundecanedioic acid, for treatment of acne and associated skin conditions.

A person of ordinary skill in the art would have been motivated, to further employ oxa diacids, such as trioxaundecanedioic acid, for treatment of acne associated skin conditions because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See In re Kerkhoven, 205 USPQ 1069.

10. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), Duffy et al. (US 5,472,699) and Wiegand et al. (US 2002/0151527, IDS), in further view of O'Halloran et al. (US 6,168,798) for reasons discussed above, and in further view of Duffy (US 5,703,122)

The prima references as a whole, do no teach expressly teach the employment of ascorbyl-phosphoryl-cholesterol in the composition for the treatment of acne and associated conditions.

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However, Duffy teaches that ascorbyl-phosphoryl-cholesterol is known to be useful in dermatological composition which contains a-hydroxyl acid, salicylic acid and/or retinoids. See, particularly, claim 1.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ ascorbyl-phosphoryl-cholesterol in the composition for treatment of acne associated skin conditions.

A person of ordinary skill in the art would have been motivated, to further employ ascorbyl-phosphoryl-cholesterol in the composition for treatment of acne associated skin conditions because ascorbyl-phosphoryl-cholesterol is known to reduce the side effect of the active ingredients herein. Further, as ascorbic acid derivatives, ascorbyl-phosphoryl-cholesterol would have been reasonably expected to be similarly useful as ascorbic acid.

Response to the Arguments

- 11. Applicants' amendments and remarks submitted February 3, 2009 have been fully considered, but are not persuasive.
- 12. The claims are drawn to treatment of enlarged skin pore by halogenated salicylic acid.

 The prior art teaches that the halogenated salicylic acid is known to be useful for treating or preventing acne and acne is one of the underlying etiologies of skin pore enlargement. Therefore, it would have been obvious to treat a subject with acne and enlarged skin pores.

Regarding applicants' assertion that there is no evidence that acne lead to enlarged skin pores, attention is directed to Perricone reference "It is an objective of this invention to provide improved compositions and methods for the treatment of acne vulgaris, both during the active phase, and for acneform scars afterwards, and for the prevention of acne and pore size reduction." (col. 3, line 15-25).

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Perricone reference discloses the general knowledge of acne. It is well-understood that

The basic lesion of acne is the microcomedo. Accumulation of sebum and keratinous debris results in a visible closed comedo, or whitehead, and its continued distension causes an open comedo, or blackhead. The dark color of blackheads is due to oxidized melanin. Blackheads and microcysts are noninflammatory lesions of acne, but some comedones evolve into inflammatory papules, pustules, or nodules, and can become chronic granulomatous lesions. The initial inflammatory cell in an acute acne papule is the CD4+T lumphocyte. Duct rupture is not a prerequisite for inflammation, which is due to the release of proinflammatory substances from the duct. When inflammation develops, neutrophil chemotaxis occurs. These neutrophils secrete hydrolytic enzymes that cause further damage and increased permeability of the follicular wall. In pustules, neutrophils are present much earlier. More persistent lesions exhibit granulomatous histology that can lead to scarring. (col. 1, line 54 to col. 2, line 3. emphasis added)

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- 13. An ordinary skill in the art would have recognized that those comedones would lead the enlargements of pore size. The Perricone reference is cited herein to show the fact and general knowledge of acne.
- 14. Applicant's remarks about inherency are untenable. It is noted that the rejections on the record are obvious type rejection. Further, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). applicants' attention is further directed to KSR Int'l Co. v. TeleflexInc., 127 S. Ct. 1727, 1741,

82 USPQ2d 1385, 1397 (2007), where the court states "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/ Primary Examiner, Art Unit 1617